

Remarks

Claims 1-3 are pending in the subject application. By this Amendment, claims 1 and 3 have been amended. In addition, the specification has been amended to correct informalities. No claim has been canceled or added. No new matter has been introduced by these amendments. Upon entry of these amendments, claims 1-3 will be before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The specification is objected to because boxes have been substituted for various other characters. By this Amendment, Applicants have corrected these informalities. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully request reconsideration. Claims 1 and 3 amended herein clearly set forth that the heterologous nucleotide sequence is SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, or SEQ ID NO: 5. Thus, the metes and bounds of each of the claims can be readily ascertained. Accordingly, reconsideration and withdrawal of the rejections under §112, second paragraph, is respectfully requested.

Claim 1 is rejected under 35 U.S.C. §103(a) as being obvious over the combined teachings of Conway *et al.*, Rabinowitz *et al.*, Pitkow *et al.*, and GenBank AF063497. In addition, claim 3 is rejected under 35 U.S.C. §103(a) as being obvious over Conway *et al.*, Rabinowitz *et al.*, Pitkow *et al.*, and GenBank AF063497 as applied to claim 1, further in view of Preston *et al.* Finally, claim 2 is rejected under 35 U.S.C. §103(a) as being obvious over either Conway *et al.*, Rabinowitz *et al.*, Pitkow *et al.*, and GenBank AF063497 as applied to claim 1, or Conway *et al.*, Rabinowitz *et al.*, Pitkow *et al.*, GenBank AF063497, and Preston *et al.* as applied to claim 3, further in view of either Mullaney *et al.* or Herold *et al.* Applicants respectfully request reconsideration because the references, even when combined, do not teach or suggest the claimed recombinant herpes simplex virus type 1.

As the Patent Office is aware, each of three basic criteria must be met in order to establish a *prima facie* case of obviousness. First, there must be an apparent reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. See *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct.

1727, 1741 (2007). In addition, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974).

Applicants respectfully submit that the Office Action has not established a *prima facie* case of obviousness. The references, even when combined, fail to teach or suggest the claimed recombinant herpes simplex virus type 1. Specifically, nowhere in any of the references or their combinations teaches or suggests the gene construct of SEQ ID NO:1. When the references fail to teach every limitation of the claims, an invention is not obvious. *See CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (holding that a determination of non-obviousness was correct when “no combination of the cited prior art, even if supported by a motivation to combine, would disclose all the limitations of the claims”).

The Office Action asserts that the AAV1 genomic sequence and the pSSV9 plasmid sequence are known in the art, and one of the possible sequences resulting from substituting a region comprising an AAV1 cap region for a region comprising a homologous AAV2 region would be the sequence of SEQ ID NO:1. The Office Action therefore concludes that the claimed invention would have been obvious to those skilled in the art (Office Action at pages 5-6).

The mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant’s invention does not make the modification or application obvious unless “there was an apparent reason to combine the known elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). An applicant’s invention is not “proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art.” *Id.*

Applicants respectfully submit that there is no reason to combine the cited references nor would there have been a reasonable expectation of success. While it is possible to generate thousands of rep2 and cap1 fragments through random fragmentation of the pSSV9 plasmid and AAV1 genomic sequences, none of the references or their combinations provides any teaching or suggestion toward the particular rep2 and cap1 sequences of SEQ ID NO:1.

It is only Applicants’ invention that provides the recombinant HSV-1, which carries the novel AAV vector. The ligation of the claimed rep2 and cap1 sequences significantly enhances packaging

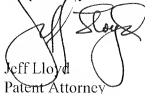
efficiency and output of rAAVs. Neither the claimed sequences nor the significant advantages for constructing such sequences is taught or suggested. None of the three basic requirements for a *prima facie* case has been established. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the claims as currently pending are in condition for allowance, and such action is respectfully requested.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Respectfully submitted,



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